

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS & AMENDMENTS

Claims 1-65 were pending in this application when last examined.

Claims 24, 25 and 34-45 were examined on the merits and stand rejected.

In item 4(a) on page 1 of the Action, claims 1-23, 26-33 and 46-65 were indicated as withdrawn as non-elected subject matter. Kindly note that claims 26 (now claim 68) and 46 (now claim 81) were erroneously indicated as withdrawn as these should have been examined with the elected invention since they are part of elected Group V (claims 24-26 and 34-46). Therefore, kindly examine new claims 68 and 81 with the elected invention.

Claims 1-21, 24-26 and 34-46 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

New claims 66-84 have been added.

To start, it is respectfully submitted that the new claims are directed to the elected invention.

New claims 66, 69 and 70 correspond to original claims 24, 34 and 35, respectively, except the new claims contain language to better conform to US format for method claims and the new claims are limited to the elected invention (wherein the identified polynucleotide is SEQ ID No: 11).

Support for the comparison and correlation to diagnosis steps in claim 66 can be found at page 23, line 29 to page 24, line 14.

New claims 67 and 68 correspond to original claims 25 and 26, respectively.

New claims 69-81 correspond to the elected invention in original claim 34-46, respectively.

New claim 82 corresponds to non-elected claim 19 with the exception that it has been revised along the lines as discussed above for new claim 66. New claims 83-84 correspond to

non-elected claims 20-21, respectively. It is respectfully requested that new claims 82-84 be rejoined with the elected invention in revised new claims 66-68 and 69-81 (original claims 24-26 and 34-36).

No new matter has been added.

Claims 22-23, 27-33 and 47-84 are pending upon entry of this amendment.

II. CLAIM OBJECTIONS

On page 2 of the Office Action, claims 24, 34 and 35 were objected to for reciting the non-elected inventions of Groups VI, VII and the non-elected sequences other than SEQ ID NO: 11.

This objection is respectfully traversed as applied to the amended and new claims.

New claims 66, 69 and 70 correspond to original claims 24, 34 and 35, except the new claims limit the method to using elected SEQ ID NO. 11 alone or in combination with SEQ ID NOS. 12 to 19.

On page 3 of the Action, claim 34 was objected to for omitting words in step (c). It is respectfully submitted that new claim 69 (which corresponds to original claim 34) overcomes this objection by using language along the lines proposed by the Examiner.

On pages 3-4 of the Action, claims 35, 36 and 44 were objected to for containing typographical errors. It is respectfully submitted that new claim 69 (original claim 36) and new claim 79 (original claim 44) overcome this objection by using language along the lines proposed by the Examiner.

In view of the above, the objections are untenable and should be withdrawn for the reasons noted above.

III. INDEFINITESS REJECTIONS

On pages 4-5 of the Office Action, claims 24, 25 and 35-45 were rejected under 35 U.S.C. § 112, second paragraph as indefinite on the basis that claims 24 and 35 omit essential steps with regard to “correlating a comparison with diagnosis” and “correlating a match with diagnosis.”

This rejection is respectfully traversed as applied to the amended and new claims. In particular, the new claims contain appropriate language for “correlating a comparison with diagnosis” and “correlating a match with diagnosis” as supported by the disclosure. Therefore, the rejection is untenable and should be withdrawn.

IV. WRITTEN DESCRIPTION REJECTION

On pages 5-9 of the Office Action, claims 24, 25 and 34-35 were rejected under 35 U.S.C. § 112, first paragraph on the basis that the specification lacks written description support for the genus of fragments of SEQ ID NO: 11 and the genus of variants of SEQ ID NO: 11. At the top of page 6 of the Action, it was indicated that the specification only discloses a polynucleotide consisting of SEQ ID NO: 11, which is not representative of the broad genus of fragments and variants.

It is respectfully submitted that the present amendment overcomes this rejection as applied to the amended and new claims.

As noted above, claims 24, 25 and 34-35 have been replaced with new independent claims 66, 69 and 70 (which correspond to original claims 24, 34 and 35, respectively). The new claims are limited to the elected invention, whereby the identified polynucleotide is SEQ ID No: 11. The new claims do not recite the “variants” and “fragments” language, which was the basis for the rejection.

Moreover, the claims are directed to methods which require using a “polynucleotide consisting of the polynucleotide sequence of SEQ ID No. 11 or a polynucleotide comprising the polynucleotide sequence of SEQ ID No. 11” as suggested at the bottom of page 8 of the Action. The Examiner indicated that this language satisfied the written description requirement. Accordingly, the claims have been amended along the lines indicated by the Examiner to comply with the written description requirement.

For these reasons, the written description rejection of claims 24, 25 and 34-35 under 35 U.S.C. § 112, first paragraph, is untenable and should be applied to the new claims.

IV. ENABLEMENT REJECTIONS

On pages 9-10 of the Office Action, claim 34 was rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification is enabled for SEQ ID NO: 11, but not for the genus of fragments and variants of SEQ ID NO: 11. The basis for this rejection is essentially the same as that for the written description rejection above.

On pages 11-18 of the Office Action, claims 24, 25 and 35-45 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks enablement for the full scope of the claimed invention for essentially the same reasons set forth for the above written description and enablement rejections. In addition, the Examiner contends that the specification is not enabling for diagnosing the genus of every liver disorder and every epithelial cancer using the genus of fragments and variants of SEQ ID NO: 11. The basis for this rejection is essentially the same as that for the written description rejection above.

It is respectfully submitted that the arguments and amendments immediately set forth above for the above written description rejection apply to the instant enablement rejections.

Again, the new claims are directed to subject matter indicated by the Examiner as enabled and supported by the disclosure. In particular, the new claims call for methods which require using a “polynucleotide consisting of the polynucleotide sequence of SEQ ID No. 11 or a polynucleotide comprising the polynucleotide sequence of SEQ ID No. 11”. It would not take undue experimentation to make and use such sequences using conventional procedures and techniques disclosed in the specification and known in the art.

For these reasons, the enablement rejection of claims 34 and the rejection of claims 24, 25 and 35-45 under 35 U.S.C. § 112, first paragraph, are untenable and should be withdrawn.

V. ANTICIPATION REJECTION

On pages 19-23 of the Office Action, claims 24, 25 and 34-45 were rejected under 35 U.S.C. § 102(b) as anticipated by Horne (WO 02/29103).

This rejection is respectfully traversed as applied to the amended and new claims.

The new claims call for methods which require using a “polynucleotide consisting of the polynucleotide sequence of SEQ ID No. 11 or a polynucleotide comprising the polynucleotide

sequence of SEQ ID No. 11".

Horne (WO 02/29103) fails to teach this sequence. Instead, Horne (WO 02/29103) discloses a polynucleotide sequence SEQ #2645 (which shares 95.6% homology to Exon 2 region of clones 5 = SEQ ID No. 11). Sequence SEQ #2645 is not the same sequence as SEQ ID NO: 11. Thus, Horne (WO 02/29103) fails to teach each and every element of the claimed invention. For this reason alone, (WO 02/29103) fails to anticipate the claimed invention.

In addition, it is respectfully submitted that the claimed diagnostic method for liver disorders (such as HCC) is novel and non-obvious in spite of the fact that the present invention involves making a match between SEQ ID No 11 or the known SEQ #2645 in Horne with corresponding nucleotides in a reference sample or reference library.

In this regard, the polynucleotide sequence SEQ #2645 in Horne (WO 02/29103) (which shares 95.6% homology to SEQ ID No. 11) is disclosed to be down-regulated in metastatic malignant liver (secondary liver cancer). This means that the polynucleotide sequence SEQ #2645 in Horne exhibits the opposite expression pattern compared to elected SEQ ID NO: 11 of the present invention, which is highly up-regulated in HCC (primary liver cancer) (see page 23, line 29 to page 24, line 14 of the instant disclosure).

Therefore, in contrast to SEQ ID NO: 11 of the present invention, sequence SEQ #2645 in Horne is not an optimal HCC biomarker, and it would not be used in the claimed method. As such, one skilled man in the art would not select SEQ #2645 (listed among other more than 800 ESTs and genes showing various pattern in primary or secondary liver cancers), because it not an optimal HCC biomarker.

For this reason, the rejection of claims 24, 25 and 34-45 under 35 U.S.C. § 102(b) as anticipated by Horne (WO 02/29103) is untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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November 13, 2006